

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

*DMB*  
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**Blood Products Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Blood Products Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on June 14, 2001, 8:30 a.m. to 5:30 p.m. and June 15, 2001, 8:30 a.m. to 3:45 p.m.

*Location:* Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD 20877.

*Contact:* Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3514, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On June 14, 2001, the following committee updates are tentatively scheduled: (1) Summary of the Public Health Service Advisory Committee on Blood Safety and Availability meeting, and (2) current thinking on clinical trial design and performance standards for approval of rapid human immunodeficiency virus (HIV) tests. In the morning, the committee will hear presentations, and discuss and make recommendations on re-entry for donors deferred because of HIV or hepatitis C virus (HCV) nucleic acid testing (NAT) or serological test results. In the

afternoon, the committee will hear presentations, and discuss and make recommendations on the Clinical Laboratory Improvement Act (CLIA) criteria for invitro diagnostic tests: (1) Applicability of waivers to HIV rapid tests, and (2) revision of the uniform donor history questionnaire. On June 15, 2001, the following updates are tentatively scheduled: Summaries of the Office of Blood Research and Review, Center for Biologics Evaluation and Research (CBER), transmissible spongiform encephalopathy (TSE) and bovine spongiform encephalopathy (BSE) action plans. In the morning, the committee will hear an informational presentation, and discuss and make recommendations on transfusion-related acute lung injury. In the afternoon, the committee will hear presentations on studies on leukoreduction filtration failures.


*Procedure:* On June 14, 2001, from 8:30 a.m. to 5:30 p.m. and on June 15, 2001, from 8:30 a.m. to 3:45 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 8, 2001. Oral presentations from the public will be scheduled between approximately 10:15 a.m. and 10:45 a.m., 2:30 p.m. and 3 p.m., and 4:45 p.m. and 5 p.m. on June 14, 2001; and between approximately 10:15 a.m. and 10:45 a.m., and 1:45 p.m. and 2:15 p.m. on June 15, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 8, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

*Closed Committee Deliberations:* On June 15, 2001, from 3:15 p.m. to 3:45 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss reports of the review of individual research programs in the Division of Hematology, Office of Blood Research and Review, CBER.

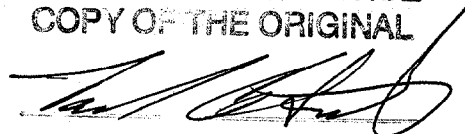
Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 5/25/01  
May 25, 2001.

  
Linda A. Suydam,  
Senior Associate Commissioner.

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